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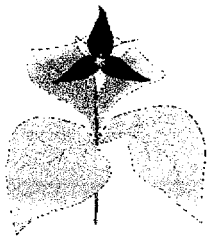

Trillium Diagnostics, LLC

5 Tamarlane
Portland, Maine 04103
PH: 207-773-5236
FAX: 207-761-2130

510(k) Summary
FETALTROL™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K002511.

Date of Summary:	August 8, 2000
Company Name:	Trillium Diagnostics, LLC 5 Tamarlane Portland, Maine 04103
Contact name:	Bruce H. Davis, MD 207-773-5236, FAX 207-761-2130
Classification name:	Hematology quality control mixture
Product name:	FETALTROL™
Product code:	JPK
CFR section:	21 CFR 864.8625
Device Class:	Class II

Device to which substantial equivalence is claimed:
Fresh umbilical cord or newborn blood (fetal red cells) mixtures as outlined in: Fetal Hemoglobin Test, manufactured by Caltag Laboratories, 1849 Bayshore Blvd, Burlingame, CA 94010, 510(k) number: K990641; Sure-Tech Fetal Hemoglobin Test, manufactured by Sure-Tech Diagnostic Associates, Inc., 11012 Lin Valle, Suite D, St. Louis, MO 63123, 510(k) number: K892241; and control cells supplied in FETALSCREEN, Ortho Diagnostic Systems, Inc. 125 Mark Ave, Carpinteria, CA 93013, 510(k) number: K820199.

Description: FETALTROL™ is an assayed control mixture for test methods that determine the quantitative or qualitative presence of fetal RBCs in maternal blood specimens. Fetaltrol is composed of human adult erythrocytes, D-antigen (Rho) negative, supplemented with human cord blood erythrocytes, D-antigen (Rho) positive, in a stabilizing medium.

Intended use: FETALTROL is a tri-level, assayed, human blood control designed to document and monitor values obtained from test methods used to determine fetal RBCs in maternal blood samples. It monitors preparation techniques, stains, reagents, and methods of data analysis for quantitative and qualitative tests.

Comparison with device of substatial equivalence: Table of Similarities and Differences between FETALTROL and the predicate device, fresh fetal or umbilical cord blood and adult blood mixtures:

Package Insert Sections	FETALTROL	Cord Blood
Intended Use	similar	similar
Summary	similar	similar
Principle	similar	similar
Reagents	human erythrocytes in a buffered salt solution with anti-microbial perservatives	human erythrocytes in a buffered salt solution
Infectious Disease Tested	YES	NO
Target Value Assignment	YES	NO
Storage	similar	similar
Stability	105 days	14 days
Indications of Deterioration	similar	similar
Performance Characteristics	similar	similar
Limitations	similar	similar
Parameters	similar	similar

Discussion of performance data: Nonclinical testing centered on the performance attributes of stability and precision and determination of substantial equivalence. FETALTROL™ passed the acceptance criteria of remaining within the assay range over the life of the product and conformed to precision limitations associated with such measurements. Expiration or shelf life dating has been established at 105 days closed vial and 25 thermal cycles open vial when stored at 2-8^{0}C and handled according to instructions for use.

Conclusions: FETALTROL™ is an effective control for assays of fetomaternal hemorrhage and counting of fetal D antigen negative (Rh_0) red cells or red cells containing HbF when used according to the instructions in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 1 2000

Bruce H. Davis, MD
President
Trillium Diagnostics, LLC
5 Tamarlane
Portland, Maine 04103

Re: K002511
Trade Name: FETALTROL™
Regulatory Class: II
Product Code: JPK
Dated: August 8, 2000
Received: August 15, 2000

Dear Dr. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number: K002511

Device Name: FETALTROL

Indications for Use:
FETALTROL is a tri-level, assayed, human blood control designed to document and monitor values obtained from test methods used to determine fetal RBCs in maternal blood samples. It monitors preparation techniques, stains, reagents, and methods of data analysis for quantitative and qualitative tests.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002511

Prescription Use ✓ OR Over –The-Counter Use _____

(Optional Format 1-2-96)